

Exhibit 1

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EXPERT REPORT

Analysis of Distributor Regulatory Compliance to Maintain Effective Controls for the Prevention of Diversion of Controlled Substances on behalf of Lake and Trumbull Counties, Ohio

Prepared by
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chargeback data, customer files, internal and external communications to include emails, written correspondence, and notes.

- Administrative investigation resulted in an Administrative Memorandum of Agreement that remained in effect for three years.

As a DEA Diversion Investigator with 13 years of experience (2004-2017), I am uniquely qualified to offer expert opinions regarding compliance with federal regulations governing the distribution of controlled substances including oxycodone and hydrocodone. I am familiar with the DEA Diversion Investigators Manual and received training from the United States Department of Justice on suspicious order monitoring, data analysis from ARCOS, reporting of suspicious orders and the due diligence required before shipping an order flagged as suspicious. I directly participated in the successful prosecution of Masters Pharmaceutical which resulted in a case opinion from the highest federal court in the country (to date). I led the first action that led to a memorandum of agreement with a manufacturer for failure to maintain effective controls to prevent diversion and failing to design and operate an adequate suspicious order monitoring system.

Based (a) on my education, training and experience, (b) the law, regulation and practices in the area of CSA enforcement, and (c) on my review of document and testimony provided in this case (MDL 2804), I am of the opinion to a reasonable degree of professional certainty that there was a systematic, prolonged failure over many years by the distributor/pharmacy defendants to maintain effective controls against diversion of legitimate opioid prescriptions into the illicit market.¹ I am further of the opinion that this systematic failure was a substantial cause of the opioid epidemic plaguing the country and specifically in Lake County and Trumbull County. I am prepared to testify regarding the regulatory duties imposed by the CSA and federal regulations. I have been asked to review the documents produced by the defendants and depositions taken in MDL2804 and other opioid litigation that I have been asked to provide opinions in and offer opinions regarding statutory and regulatory compliance.

I offer my opinions herein to a reasonable degree of professional certainty. I believe the facts stated herein are true and accurate and based on the record provided to me. I understand that the defendants continue to supplement discovery and have disclosed hundreds of thousands of documents. I have relied upon the defendants' answers to discovery requests as a basic outline for evidence of compliance to reach my opinions.

I am being compensated at the rate of \$300.00 per hour for the time I have spent related to this report. The hourly rate for my time spent testifying is \$500.00 per hour. I have not previously provided expert testimony at trial. I have provided expert testimony by deposition in *In re: National Prescription Opiate Litigation*, MDL No. 2804 (Case Track One and Case Track Two) and in the New York State litigation, *In re Opioid Litig.*, Index No. 400000/2017. I have not authored any publications or articles. In addition to the documents and testimony cited within my report, I have also reviewed documents identified in the attached Schedule I.

¹ I provide all opinions in this report with a reasonable degree of professional certainty.

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II. OPINIONS

Based on my education, background, experience, and review of the documents produced in this matter and provided to me, my opinions, which are more fully set forth throughout this report, are as follows:

1. The Controlled Substance Act (CSA) is designed to provide for a closed delivery system related to the pharmaceutical supply chain. The CSA requires DEA registration for each member of the closed supply chain, known as a registrant. This is due to the dangerous and abusive nature of the controlled substances that flow through the pharmaceutical supply chain.
2. As a member of the closed delivery system each registrant takes on certain statutory and regulatory obligations to ensure the safety and efficiency of the pharmaceutical supply chain. These statutory and regulatory duties have remained the same since the enactment of the CSA.
3. The pharmaceutical supply chain flows from manufacturer (labeler) to wholesale distributor and then to the end dispenser (pharmacy, hospital, practitioner). This gives the distributors a unique position in the supply chain in that they are the last checkpoint before the controlled substances go to the end dispenser.
4. Under the CSA and the implementing regulations the distributors have two significant obligations that are designed to ensure that these controlled substances do not veer outside of the closed supply chain. These statutory and regulatory obligations come from:
 - 21 U.S.C.A. § 823(b)(1); which requires the “maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels.”
 - 21 C.F.R. § 1301.74(b); which require the registrant to “design and operate a system to disclose to the registrant suspicious orders of controlled substances.” Then the registrant is required to notify the DEA of all identified suspicious orders prior to shipment.
5. Each of these obligations play a vital role in protecting the integrity of the pharmaceutical supply chain. It is up to each registrant to design a system, often referred to as a suspicious order monitoring system (SOMS), that will comply with these regulatory requirements based on the differing type of business models they choose as customers. For example, a wholesale distributor that only services hospitals would need a SOMS different from that for one who services veterinary clinics.

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6. CVS, Walmart, Walgreens, Rite Aid and HBC/Giant Eagle each failed to develop and implement a SOMS that would ensure the maintenance of effective controls against diversion. While each of them had different systems for which they implemented each of these systems were either faulty in their design or in the manner they were operated.
7. CVS, Walmart, Walgreens, Rite Aid and HBC/Giant Eagle each failed to develop a comprehensive system to monitor, detect, and report all suspicious orders of opioids placed by pharmacies in Lake and Trumbull Counties. This failure is exacerbated as there were significant timeframes when the Defendants would identify suspicious orders and still ship the orders to the respective pharmacies.
8. CVS, Walmart, Walgreens, Rite Aid and HBC/Giant Eagle each failed to conduct adequate due diligence on suspicious orders of opioids placed by pharmacies in Lake and Trumbull Counties, to determine whether the customer was engaged in diversion;
9. CVS, Walmart, Walgreens, Rite Aid and HBC/Giant Eagle each distributed opioids to pharmacies in the Lake and Trumbull Counties in disproportionately excessive amounts without adequately documenting justification; and
10. CVS, Walmart, Walgreens, Rite Aid and HBC/Giant Eagle each failed to halt suspicious shipments of opioid orders to pharmacies in Lake and Trumbull Counties they knew, or should have known, were going to be diverted.

III. STANDARDS

A. STATUTORY DUTY.

Each distributor/pharmacy owes a duty to *maintain effective control* against diversion of prescription opiates into the illicit market. 21 U.S.C.A. § 823(b)(1) [1970].

The Controlled Substances Act (“CSA”) and its implementing regulations create restrictions on the distribution of controlled substances. *See* 21 U.S.C. §§ 801–971 (2006); 21 C.F.R. §§ 1300–1321 (2009). The main objectives of the CSA are to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances. Congress was particularly concerned with the need to prevent the diversion of drugs from legitimate to illicit channels. To effectuate these goals, Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA. The CSA categorizes all controlled substances into five schedules. The drugs are grouped together based on their accepted medical uses, the potential for abuse, and their psychological and physical effects on the body. Each schedule is associated with a distinct set of controls regarding the manufacture, distribution, and use of the substances listed therein. The CSA

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distributors, such as those considered in this report, have total visibility of all orders placed by their affiliated pharmacies to any distributor. Therefore chain pharmacy distributors must consider and take into account orders placed to third-party distributors when determining whether orders from affiliated pharmacies are suspicious. The suspicious order monitoring system failures described above directly led to massive quantities of pills being shipped to buyers who had placed suspicious orders of controlled substances. These orders never should have shipped until after the suspicion of diversion was dispelled.

IV. Identifying Suspicious Orders Distributed in Lake and Trumbull Counties, Ohio

I have described in this report the ways in which the defendants' inadequate response to their statutory and regulatory requirements to maintain effective controls related to the sales of prescription opioids would potentially cause the diversion of these pills for non-medical use. I have reviewed seven suspicious order methodologies, some of which were utilized by one or more of the defendants. These methodologies are identified in the April 16, 2021 report of Craig J. McCann, Ph.D., CFA as "Maximum Monthly, Trailing Six-Month Pharmacy Specific Threshold," "Trailing Six-month Maximum Monthly, Fixed After First Triggered Threshold," "Twice Trailing Twelve-month Average," "Three Times Trailing Twelve-month Average," "Maximum 8,000 Dosage Units Monthly," "Maximum Daily Dosage Units," and "Maximum Monthly Trailing Six Month Specific Threshold on Rolling 30 Days." Dr. McCann applied these methodologies to each defendant's distributions of opioids into Lake and Trumbull County as well as, separately, to opioid orders from all distributors to each defendant's affiliated chain pharmacies. The purpose of each system was to identify suspicious orders that should not have been shipped unless the distributors' due diligence eliminated the suspicion of diversion. Each method would have identified a significant volume of orders of opiates as shown in the tables below.¹¹⁸

With the exception of the methodology titled Trailing Six-month Maximum Monthly, Fixed After First Triggered Threshold,¹¹⁹ under each of these methodologies, once an order by a pharmacy is flagged and the distributor does not conduct sufficient due diligence to dispel the suspicion of diversion, each subsequent order by that pharmacy is also flagged. The failure to conduct adequate due diligence on the initial triggering order, means that all subsequent orders by that pharmacy are likewise suspicious. This is consistent with the testimony of Thomas Prevoznik

¹¹⁸ I utilized these Defendants - CVS, Walgreens, Walmart, HBC/Giant Eagle, and Rite Aid - as they constitute a significant majority of the opioid pills delivered into CT3 according to the data described in the Expert Report of Craig J. McCann.

¹¹⁹ Under the Trailing Six-month Maximum Monthly, Fixed After First Triggered Threshold, when a transaction causes the number of dosage units shipped to a pharmacy in a month to exceed the highest number of dosage units shipped to the pharmacy in any one of the six preceding months, the dosage units of highest month in the preceding six months becomes threshold which is then applied in all subsequent months.

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Enforcement Administration, 861 F.3d 206 (2017) provides a reasonable estimate and an initial trigger and first step to identifying orders of unusual size.¹²⁴ See Methodology A above. Pursuant to *Masters*, “as a matter of common sense and ordinary language, orders that deviate from a six-month trend are an ‘unusual’ and not ‘normal’ occurrence” *Masters Pharm., Inc. v. Drug Enf’t Admin.*, 861 F.3d 206, 216 (D.C. Cir. 2017). I say this understanding that this litigation will be advanced by selecting a methodology quantifying a volume of pills that entered CT3 jurisdictions unlawfully and providing this data to an economist to measure the harm caused by this volume.

Based on my education, background, and experience, as well as my review of relevant documents, the absence of adequate distributor due diligence and failure to respond to indicators of suspicious orders as described in this report constitutes the Defendants’ failures to comply with the requirements of the Controlled Substances Act. It is further my opinion that this misconduct led to the excess quantity of opiate pills flooding the illicit market in CT3 jurisdictions.

V. REGISTRANT SUSPICIOUS ORDER MONITORING SYSTEMS (SOMS)

I have been asked to review the documents produced in this litigation to determine whether the distributors complied with the statutory and regulatory duties outlined above. In this process I have reviewed numerous documents and depositions for each of the enumerated Defendants. Based on my review it is my opinion to a reasonable degree of professional certainty that each of the distributors failed to comply with their statutory and regulatory duty to maintain effective controls to prevent diversion and to design and operate a system to identify and report suspicious orders.

A. CVS Health

Distribution Center	DEA Registrant Number
CVS Indiana, L.L.C. 7590 Empire Drive, Doors 116-123 Indianapolis, Indiana 6219	RH0197170
CVS Rx Services, Inc. 150 White Wagon Road Chemung, New York 14825	RC0415871
CVS TN Distribution, L.L.C. 10017 Kingston Pike Knoxville, Tennessee 37922	PR0205559

Transactional Data:

Date range: 2006-2014 (ARCOS)

Volume:

¹²⁴ This approach does not take into consideration unusual pattern or frequency.

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8. **Shipping Requirement:**

Despite representing to its upstream vendors that it screened and stopped suspicious shipments from shipping, Giant Eagle did not have the ability to automatically stop orders from shipping which exceeded its set threshold during the period that Giant Eagle shipped controlled substances.⁷⁰⁰

Giant Eagle also did not manually stop suspicious orders from shipping which had been flagged by its threshold report. Giant Eagle admitted that its threshold reports tracked already shipped, not ordered materials,⁷⁰¹ which did not leave an adequate window or process to identify, stop and investigate unusual orders once it became aware of them.

After Giant Eagle stopped shipping prescription opioids through HBC, it had the opportunity for GERX DC to utilize a third-party system to stop over-threshold orders from shipping. Giant Eagle's Senior Pharmacy Director Adam Zakin declined, claiming it was not worth the expense because the only thing the new system would do was "stop the orders physically if there were a threshold."⁷⁰²

By: 
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April 16, 2021

⁷⁰⁰ HBC_MDL00029196; ENDO_HSGAC_0007618 at -0007621; HBC_MDL00169476; Tsipakis 12/13/18 Depo., 213:8–10, 255:24–256:23; HBC_MDL00028498.

⁷⁰¹ Tsipakis 12/13/18 Depo., 141:3–11.

⁷⁰² HBC_MDL00028498, email, March 29, 2016.